

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

5:07CV0514

UNITED STATES OF AMERICA, )  
 )  
Plaintiff, )  
 )  
v. )  
 )  
HOLMES BY-PRODUCTS CO., INC., )  
a corporation, and )  
ABE L. MILLER, and )  
DENNIS K. KOSHMIDER, )  
individuals, )  
 )  
Defendants. )  
\_\_\_\_\_ )

Civil No. \_\_\_\_\_

JUDGE GWIN  
CONSENT DECREE OF  
PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against defendants Holmes By-Products Co., Inc., a corporation, and Abe L. Miller and Dennis K. Koshmider, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and Plaintiff having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by causing the introduction into interstate commerce of food, within the meaning of 21 U.S.C. § 321(f), namely chicken by-product meal, a type of poultry by-product meal, that is misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and 321(n).

4. Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a), from manufacturing, processing, labeling, holding for sale, and distributing, at or from Defendants' facility located at 3175 TR 411, Millersburg, OH 44654 (the "facility") and any other location(s) at or from which Defendants manufacture, process, label, hold for sale, or distribute, food, including poultry by-product meal, unless and until:

A. Defendants' have submitted to FDA within ten (10) days of the entry of this Decree their written decision to pursue the steps described in subparagraphs 1, 2, and/or 3 below, and FDA has approved such decision in writing.

1. In a manner acceptable to FDA, Defendants shall prominently label their poultry by-product meal, which contains or may contain "protein derived from mammalian tissues," as defined at 21 C.F.R. § 589.2000(a)(1) with the cautionary statement "Do not feed to cattle or other ruminants," and shall affix such statement to all requisite labeling associated with the product. Within ten (10) days of electing to proceed under this subparagraph, Defendants shall submit examples of the new label and appropriate documentation as described above to FDA. After review, FDA shall provide written notification to Defendants stating whether the submissions are approved. If the submissions are not approved, Defendants shall make any necessary corrections, as deemed necessary by FDA.

2. Defendants shall obtain new equipment that is exclusively dedicated to the production of poultry by-product meal and that is sufficiently clean and sanitized so as to prevent contamination or commingling of the poultry by-product meal with protein derived from mammalian tissues. This subparagraph does not prevent Defendants from using newly purchased equipment for producing material containing protein

derived from mammalian tissues if Defendants are otherwise complying with subparagraphs 4(A)(1) or 4(A)(3), and Defendants' use of the new equipment is otherwise lawful.

3. Defendants shall clean and sanitize the facility and all equipment used to manufacture, process, label, hold for sale, or distribute poultry by-product meal, in a manner sufficient to remove encrusted residues on such equipment and develop written clean-out procedures, which ensure that poultry by-product meal will continuously be manufactured, processed, labeled, held for sale, and distributed in compliance with 21 C.F.R. § 589.2000, and under conditions that will continuously prevent contamination or commingling of the poultry by-product meal with protein derived from mammalian tissues. Should Defendants elect this option, they shall:

a. Retain a person(s) ("expert"), who is without any personal or financial ties (other than the agreement) to Defendants and their families, and who, by reason of background, training, or experience, is qualified to develop and implement procedures to comply with paragraph 4(A)(3), the Act, and FDA regulations; and

b. Retain a laboratory ("laboratory"), that by reason of staff and experience, is qualified to analyze Defendants' poultry by-product meal by feed microscopy, to determine whether Defendants' poultry by-product meal contains

mammalian tissue. Defendants must submit a written plan ("analysis plan") acceptable to FDA detailing the process and procedures Defendants propose to use to ensure that each batch or lot of poultry by-product meal is analyzed by the laboratory before it is released for distribution. Defendants shall not implement the analysis plan until they have received written approval from FDA to do so. Defendants shall obtain the results of the laboratory's analysis prior to release for distribution; maintain a written copy of the laboratory's analysis report for each batch or lot of poultry by-product meal that is released for distribution; retain these records for the entire time the Decree remains in effect; and shall make these records immediately available to FDA upon request to verify Defendants' compliance with the terms of this Decree. When any sample collected under this subparagraph reveals the presence of mammalian tissue, Defendants shall notify FDA immediately via telephone, and shall provide FDA with written results of analyses conducted by the laboratory within two (2) business days of Defendants' receipt. Unless Defendants' analysis plan provides for the continued labeling of product pursuant to subparagraph 4(A)(1) of this Consent Decree, Defendants shall not release for distribution the batch or lot from which the positive sample was taken.

B. Under the supervision of and in accordance with methods acceptable to FDA, Defendants have destroyed, or

otherwise brought into compliance with the Act and all applicable regulations, all misbranded lots of poultry by-product meal at the facility and/or under Defendants' custody or control on and after the date of entry of this Decree within thirty (30) days of approval of such a plan by FDA, as described in the next sentence. Defendants shall not destroy or attempt to bring into compliance with the Act any of the poultry by-product meal on hand at their facility or under their custody or control at the time of entry of this Decree until Defendants have submitted to FDA, and FDA has approved in writing, a written plan describing the method of destruction and/or the method Defendants propose to use to bring the poultry by-product meal into compliance with the Act and all applicable regulations. Defendants shall notify FDA in writing no less than five (5) business days before they destroy any product and or attempt to bring any portion of the poultry by-product meal on hand at the time of entry of this Decree into compliance with the Act and applicable regulations. In order to effectuate its commitment under this subparagraph, FDA may inspect Defendants' facility and require such additional corrective measures as it deems necessary to ensure Defendants' continuous compliance with the Act, FDA regulations, and this Decree; and

C. Defendants have paid FDA for all costs, incurred between the date of entry of this Decree and the date of FDA

approvals pursuant to subparagraphs A, B, and D for inspections, supervision, and analytical work performed by FDA, at the rates specified in paragraph 8; and

D. Defendants' have adequately implemented the procedures under subparagraphs A and B and have received written confirmation from FDA that Defendants' appear to be in compliance with this Decree.

5. If, at any time after receiving FDA approval to operate under one of the options set forth in paragraph 4(A), Defendants desire to change their election, Defendants shall submit a written request to FDA specifying under which subparagraph(s) they wish to operate. Defendants shall not operate under a proposed new option until Defendants receive written FDA approval to make the change. Upon receiving written FDA approval, Defendants shall comply with the terms of the new option(s) chosen, except that, in the event that Defendants choose to discontinue the production of prohibited material at their facility, the requirements set forth in subparagraph 4(A)(3)(b) shall continue until the results of laboratory analysis for five (5) consecutive complete batches reveal no presence of mammalian tissue.

6. After Defendants have complied with paragraph 4 and have received written notification from FDA as specified in paragraphs 4(A), 4(B), and 4(D), above, Defendants and each and all of their

officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined from: (1) directly or indirectly causing the introduction into interstate commerce of any article of food, within the meaning of 21 U.S.C. § 321(f), that is misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and 321(n) and 21 C.F.R. § 589.2000(g)(2); and (2) failing to implement and continuously maintain the requirements of this Decree.

7. Representatives of FDA shall be permitted, without prior notice, and as and when FDA deems necessary, to make inspections of Defendants' facility(s), at its current location or at any new location(s), and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include, but are not limited to, the taking of photographs and samples and the examination and copying of all records that relate to the manufacturing, processing, labeling, holding for sale, or distributing of any food. Such inspections shall be permitted upon presentation of a copy of this Decree, appropriate credentials, and the giving of written notice specifying that such inspection is being conducted pursuant to

the Order of this Court. Such inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall pay the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: \$76.10 per hour and fraction thereof per representative for inspection work; \$91.18 per hour or fraction thereof per representative for analytical or review work; \$0.445 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

9. If any Defendant violates this Decree and is found in civil or criminal contempt, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorney fees

(including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

10. Defendants shall immediately cease manufacturing, processing, labeling, holding for sale, and distributing poultry by-product meal if, based on the results of an inspection, analysis of a sample or samples, or other information, FDA notifies Defendants in writing that any article of food in the plant is misbranded or that Defendants are not in compliance with the terms of this Decree, the Act, or FDA regulations. In addition, Defendants shall, as and when FDA deems necessary, recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. All costs of such recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, investigations, supervision, reviews, examinations, and analyses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in paragraph 8. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

11. Any cessation of operations as described in paragraph 10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, FDA regulations, and this Decree.

12. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships).

13. Defendants shall provide to FDA an affidavit of compliance within twenty (20) calendar days after the date of the entry of this Decree stating the fact and manner of compliance with paragraph 12 and identifying the names and positions of all persons who were so notified.

14. Defendants shall post a copy of this Decree on a bulletin board in the employee common area at Defendants' facility within ten (10) calendar days of the entry of this Decree, and shall ensure that the Decree remains posted so long as the Decree remains in effect.

15. After entry of the Decree, Defendants shall, within ten (10) calendar days of employment of any new employee, provide such employee a copy of the Decree, by personal service or by certified mail, return receipt requested.

16. Defendants shall notify FDA, in writing, at least thirty (30) calendar days before any changes in ownership, name,

or character of the business that occurs after the entry of this Decree, including a reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of Holmes, or any other current or future rendering business of Defendants'; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect compliance obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business. Defendants shall furnish to FDA, and to the Plaintiff's attorneys, an affidavit of compliance with this paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

17. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Cincinnati Office, 6751 Steger Drive, Cincinnati, Ohio 45237. For purposes of paragraph 4(A)(3)(b), telephone correspondence shall be made to (513) 679-2700.

18. All decisions specified in this Decree shall be vested in the sole discretion of FDA, which discretion, if challenged by Defendants, shall be reviewed under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based

exclusively upon the written record that was before FDA at the time of the decision. No discovery may be had by either party.

19. Plaintiff, the United States, shall have and recover from Defendants the costs of this action as taxed by the Court.

20. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

SO ORDERED:


Dated this 23 day of February, 2007.

s/ James S. Gwin

United States District Judge

We hereby consent to the entry of the foregoing Decree.

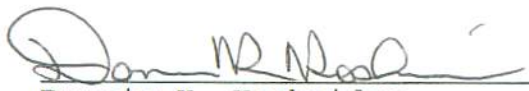
For Defendants:

  
Abe L. Miller  
President  
Holmes By-Products Co., Inc.  
Individually, and on behalf  
of Holmes by-Products  
Co., Inc.


For Plaintiff:

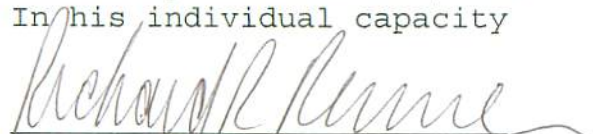
Gregory A. White  
United States Attorney  
Northern District of Ohio

Alex Rokakis  
Assistant U.S. Attorney

  
Dennis K. Koshmider  
Vice President/General Manager  
Holmes By-Products Co., Inc.  
In his individual capacity

By:

  
Joel D. Schwartz  
Trial Attorney  
Office of Consumer Litigation  
Department of Justice  
P.O. Box 386

  
Richard Renner

1331 Pennsylvania Ave., N.W.  
Room 950 North

Tate & Renner  
505 N. Wooster Avenue

P.O. Box 8  
Dover, OH 44622-0008  
Counsel for:  
Abe L. Miller  
Dennis K. Koshmider  
Holmes by-Products Co., Inc.

Washington, D.C. 20004

OF COUNSEL:

Daniel Meron  
General Counsel

Sheldon T. Bradshaw  
Chief Counsel  
Food and Drug Division

Eric M. Blumberg  
Deputy Chief Counsel for  
Litigation

Jessica L. Zeller  
Assistant Chief Counsel

United States Department of  
Health and Human Services  
Office of the General Counsel  
5600 Fishers Lane  
Rockville, MD 20857  
301-827-8577